

REMARKS

Reconsideration and withdrawal of the rejections of the pending claims are respectfully requested in view of the amendments and remarks herein, which place the application in condition for allowance.

**I. STATUS OF CLAIMS AND FORMAL MATTERS**

Claims 1-36 are now pending in this application. Claims 26-29 and 33 are subject to examination based on the elections with traverse by the applicants. Claims 1-25, 30-32 and 34-36 are withdrawn although the applicants believe that claims 1-7 and 35 and 36 should also be included in the examination or should be rejoined when the examined claims are allowed.

Claims 1, 8, 19, 26, 30 and 33 have been amended for clarification. No new matter has been added by this amendment.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited in the Office Action, and that these claims were in full compliance with the requirements of 35 U.S.C. §112. It is submitted that the amendments of the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

The issues raised by the Examiner in the Office Action are addressed below in the order they appear in the prior Action.

**II. THE REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH, IS OVERCOME**

Claims 26-29 and 33 are rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as invention.

The Examiner contends that the way of attachment of “H<sub>2</sub>N-CS” in formula II is not clearly defined. The Examiner asserts that on page 22 C=S is connected to formula II via carbon, while page 37 shows -S- connected to pyrazole of formula III.

Claims 1, 8, 19, 26, 30, and 33 are amended to recite R<sup>1</sup> as H<sub>2</sub>N-C(=S)-, thereby obviating the rejection. Thioamide group, H<sub>2</sub>N-C(=S)-, at C-3 position of pyrazole of formula II is connected to it via carbon atom as it is correctly depicted on page 7, paragraph 0161 of the specification as published. Support for the term “thioamide” can be found throughout the specification as published (for example in paragraphs 0189, 0190, 0251, 0826, 0828, 0829, 0831, etc.). Compound of formula III cited by the Examiner is not a thioamide, as it has CN at C-3 position. Sulfur atom mentioned by the Examiner as a point of attachment, belongs to SCF<sub>3</sub> group at C-4 position of pyrazole of formula III.

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph, are respectfully requested.

### **III. THE 35 U.S.C. §102 REJECTION IS OVERCOME**

Claims 26-29 and 33 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by ALIG *et al.* (U.S. Patent No. 6,518,296).

It is respectfully pointed out that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention. *See Lewmar Marine Inc. v. Bariant Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Second, the prior art must contain an enabling disclosure. *See Chester v. Miller*, 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). A reference contains an enabling disclosure if a person of ordinary skill in the art could have combined the description of the invention in the prior art reference with his own knowledge of the art to have placed himself in possession of the invention. *See In re Donohue*, 226, U.S.P.Q. 619, 621 (Fed. Cir. 1985).

Although the Applicant does not agree with the rejection, in the interest of expediting prosecution, claims 1, 8, 19, 26, 30, and 33 have been amended. ALIG *et al.* does not teach or suggest the compounds of formula (II) disclosed in these claims as amended. Therefore, claims 26 and 33, as amended, and by dependency, claims 27-29 are not anticipated by ALIG *et al.*

Also, ALIG *et al.* does not teach or suggest the premix formulations comprising compound of formula (II) and pharmaceutically acceptable wax, antioxidant and a pH modifier. As such, ALIG *et al.* does not teach or suggest all the elements of the pending claims as amended.

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) are respectfully requested.

#### **IV. THE 35 U.S.C. §103 REJECTION IS OVERCOME**

Claims 26-29 and 33 are rejected under 35 U.S.C. §103(a) as being unpatentable over SOLL *et al.* (U.S. Patent No. 7,262,214) and ALIG *et al.* (U.S. Patent No. 6,518,296) in view of BUNTAIN *et al.* (U.S. Patent No. 4,963,575).

Applicants respectfully submit that SOLL *et al.* does not meet the criteria to be qualified as prior art under 35 U.S.C. §102 (a)/(b) and (e) rendering the rejection under 35 U.S.C. §103 improper. SOLL *et al.* is not available under 102(a) or (b) as its earliest publication was after the effective filing date of the present application.

MPEP § 706.02(k) states that

“[e]ffective November 29, 1999, subject matter which was prior art under former 35 U.S.C. § 103 via 35 U.S.C. § 102(e) is now disqualified as prior art against the claimed invention if that subject matter and the claimed invention ‘were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.’ This change to 35 U.S.C. § 103(c) applies to all utility, design, and plant applications filed on or after November 29, 1999...”

As SOLL *et al.* and the instant application share common inventors and are commonly assigned to Merial Limited, it cannot properly be considered as a reference under 35 U.S.C. §103(a), as 35 U.S.C. §102(e) expressly forbids such a reference from “precluding patentability.” This reference is not by “another,” as required by Section 102(e). (The assignment of the present application is set out at reel 015951, frame 0385.) Accordingly, it is respectfully requested that the rejection of claims under 35 U.S.C §103(a) as being unpatentable over SOLL *et al.* (U.S. Patent No. 7,262,214) be withdrawn.

Establishing a *prima facie* case of obviousness requires that the prior art reference (or references when combined) must teach or suggest all the claim limitations. The Examiner is respectfully reminded of the case law, namely, that there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27

U.S.P.Q. 2d 1063 (BOPAI 1993). As stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): “The mere fact that the prior art may be modified in the manner suggested by the Office Action does not make the modification obvious unless the prior art suggests the desirability of the modification.” Also, the Examiner is respectfully reminded that for the Section 103 rejection to be proper, both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants’ disclosure. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). Furthermore, the Supreme Court has recently reaffirmed the factors set out in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18: “[T]he scope and content of the prior art are determined; differences between the prior art and the claims at issue are...ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.” *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_\_ (2007).

Neither ALIG *et al.* nor BUNTAIN *et al.*, alone or in combination, teach or suggest a premix formulation comprising a compound of formula (II) and pharmaceutically acceptable wax, antioxidant and a pH modifier disclosed in claims 26 and 33 as amended.

For the foregoing reasons, the references cited by the Examiner do not render the claimed subject matter *prima facie* obvious. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. §103(a) are respectfully requested.

**REQUEST FOR INTERVIEW**

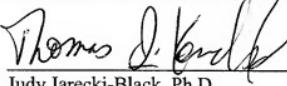
If any issue remains as an impediment to allowance, prior to issuance of any paper other than a Notice of Allowance, an interview, is respectfully requested, with the Examiner his supervisor, and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the remarks and amendments herein, and prompt issuance of a Notice of Allowance is respectfully requested.

Respectfully submitted,  
MERIAL LTD.  
FROMMER LAWRENCE & HAUG LLP

By:

  
Judy Jarecki-Black, Ph.D.  
Reg. No. 44,170  
Tel. No. (678) 638-3805  
Fax No. (678) 638-3350  
Thomas J. Kowalski  
Reg. No. 32,147